

Translation

PATENT COOPERATION TREATY

PCT/JP2003/014423



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P03-128	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/014423	International filing date (day/month/year) 13 November 2003 (13.11.2003)	Priority date (day/month/year) 13 November 2002 (13.11.2002)
International Patent Classification (IPC) or national classification and IPC C12N 9/02, 15/53, C12Q 1/26		
Applicant TOYO BOSEKI KABUSHIKI KAISHA		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☒ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) disk, 1, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
- This report contains indications relating to the following items:
 - ☒ Box No. I Basis of the report
 - ☐ Box No. II Priority
 - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☒ Box No. IV Lack of unity of invention
 - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Box No. VI Certain documents cited
 - ☐ Box No. VII Certain defects in the international application
 - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 05 March 2004 (05.03.2004)	Date of completion of this report 22 November 2004 (22.11.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/014423

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☒ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
 - ☒ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:

The inventions of claims 1-17 and 18-30 hold in common the fact that they concern modified sarcosine oxidases.

However, as described in JP 7-163341 A and JP 10-248572 A, the preparation of a modified sarcosine oxidase is a publicly known matter, and therefore it cannot be recognized as a special technical feature in the sense of PCT Rule 13.2 (2). In addition, no other common matter that can be considered a special technical feature in the sense of PCT Rule 13.2 (2) is present among the modified sarcosine oxidases of claims 11-17 and 18-32.

The same opinion applies to the inventions of claims 1-17 and 31-34.

The inventions of claims 18-30 and 31-34 hold in common the fact that they concern modified sarcosine oxidases with reduced activity toward L-proline.

However, as described in JP 10-248572 A, the preparation of a modified sarcosine oxidase with reduced activity toward L-proline is a publicly known matter, and therefore it cannot be recognized as a special technical feature in the sense of PCT Rule 13.2 (2). In addition, no other common matter that can be considered a special technical feature in the sense of PCT Rule 13.2 (2) is present among the modified sarcosine oxidases of claims 18-30 and 31-34.

4. Consequently, this report has been established in respect of the following parts of the international application:

☒ all parts.

☐ the parts relating to claims Nos. _____

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/14423

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-5, 18-22, 29-41	YES
	Claims	6-17, 23-28	NO
Inventive step (IS)	Claims	1-5, 18-22, 29-41	YES
	Claims	6-17, 23-28	NO
Industrial applicability (IA)	Claims	1-41	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: JP 7-163341 A

Document 2: JP 10-248572 A

Based on the description in document 1 cited in the international search report, the inventions of claims 1-5 and 35-38 lack novelty. The modified sarcosine oxidase described in document 1 is stated to be stable in a transformant homogenate (column 0029, etc.) Stability in this transformant homogenate is equivalent to the "stability in a liquid state" of this application.

Based on the description in document 2 cited in the international search report, the inventions of claims 18-22 and 29-41 lack novelty. The modified sarcosine oxidase described in document 2 has reduced reactivity toward proline. In addition, document 2 states that said sarcosine oxidase has almost no loss of absolute enzymatic performance (column 0038, etc.), and this examination finds that the K_m value with respect to sarcosine is almost unchanged by the modification. In addition, document 2 describes a reagent for creatine measurement and a reagent for creatinine measurement that contain this modified sarcosine oxidase (Claims 9 and 10, etc.)

Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing.
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purpose of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

** If item 4 in Box No. 1 applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*